CAUSE NO. 12-09885

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| STATE OF TEXAS,<br>Plaintiff | § | IN THE DISTRICT COURT OF |
| VS. | § | DALLAS COUNTY TEXAS |
| JANSSEN PHARMACEUTICALS, INC.;<br>AND JOHNSON & JOHNSON<br>Defendants | § | ____ JUDICIAL DISTRICT |

**PLAINTIFF'S ORIGINAL PETITION**

1. Plaintiff, THE STATE OF TEXAS, acting by and through Attorney General Greg Abbott, brings this action complaining of Defendants JANSSEN PHARMACEUTICALS, INC. and JOHNSON & JOHNSON for violating the TEXAS DECEPTIVE TRADE PRACTICES--CONSUMER PROTECTION ACT, TEX. BUS. & COM. CODE §§17.41 et seq. ("DTPA"), as follows:

**AUTHORITY**

2. This action is brought by Attorney General Greg Abbott, through his Consumer Protection Division, in the name of the STATE OF TEXAS and in the public interest under the authority granted him by §17.47 of the Texas Deceptive Trade Practices - Consumer Protection Act, TEX. BUS. & COM. CODE ANN. §17.41 et seq. ("DTPA"), upon the grounds that Defendants have engaged in false, misleading or deceptive acts or practices in the course of trade and commerce as defined in, and declared unlawful by §§17.46(a) and (b) of the DTPA.

## PARTY DEFENDANTS

3. Defendant Janssen Pharmaceuticals, Inc. ("Janssen") is a Pennsylvania corporation with its principal place of business at 1125 Trenton Harbourton Road, Titusville, New Jersey, and is a wholly-owned subsidiary of Johnson & Johnson. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Defendant Janssen and Defendant Johnson & Johnson, through its wholly-owned subsidiary Janssen, transacts business in Texas and nationwide by manufacturing, marketing, promoting, selling and distributing atypical antipsychotic prescription drugs containing risperidone or paliperidone, the most popular product is known by the trade name Risperdal (which includes Risperdal Consta and Risperdal M Tab).

## VENUE

4. Venue of this action lies in Dallas County on the basis of §17.47(b) of the DTPA because Defendants' acts and practices that violate these statutes occurred throughout Texas, including Dallas County, Texas.

## PUBLIC INTEREST

5. Because Plaintiff STATE OF TEXAS has reason to believe that Defendants have engaged in, and will continue to engage in, the unlawful practices set forth below, Plaintiff STATE OF TEXAS has reason to believe that Defendants have caused and will cause adverse effects to legitimate business enterprises which conduct their trade and commerce in a lawful manner in this State. Therefore, the Attorney General of the STATE OF TEXAS believes and is of the opinion that these proceedings are in the public interest.

## ACTS OF AGENTS

6. Whenever in this petition it is alleged Defendants did any act or thing, it is meant that Defendants performed or participated in such act or thing or that such act was performed by agents or employees of Defendants and in each instance, the agents or employees of Defendants were then authorized to and did in fact act on behalf of Defendants or otherwise acted under the guidance and direction of Defendants.

## TRADE AND COMMERCE

7. Defendants have, at all times described below, engaged in conduct which constitutes "trade" and "commerce" as those terms are defined by §17.45(6) of the DTPA.

## NOTICE BEFORE SUIT

8. Plaintiff informed Defendants herein at least seven (7) days before instituting this action of the alleged unlawful conduct of which complaint is now made.

## DEFENDANTS' CONDUCT

9. Risperdal is one of several second-generation antipsychotic prescription drugs (also referred to as "atypical antipsychotics") developed to reduce some of the side effects caused by traditional antipsychotic drugs.

10. In January 1994, Janssen launched Risperdal, the trade name for its atypical antipsychotic drug containing the chemical risperidone. At the time, the only Food and Drug Administration ("FDA")-approved indication for Rispderal use was for "the management of manifestations of psychotic disorders" in adults.

11. In September 2000, the FDA narrowed the approved indication and use for Risperdal from "indicated for the management of the manifestations of psychotic

disorders" to "indicated for the treatment of schizophrenia."

12. In 2003, the FDA approved Risperdal M-Tab (an orally dissolving form of Rispderal) and Risperdal Consta (a long-acting injectible form of Risperdal) for the treatment of schizophrenia in adults.

13. The FDA subsequently approved Risperdal for the following indications: as monotherapy for the short-term treatment of acute manic or mixed episodes associated with Bipolar I Disorder in adults; as adjunctive therapy, with lithium or valproate, for the short-term treatment of acute manic or mixed episodes associated with Bipolar I Disorder in adults; the treatment of irritability associated with autistic disorder in children and adolescents; the treatment of schizophrenia in adolescents ages 13-17; and for the short-term treatment of manic or mixed episodes of Bipolar I Disorder in children and adolescents ages 10-17.

14. The FDA has never approved the use of Risperdal by adults, children, or the elderly for the treatment of depression, anxiety, attention deficit disorder ("ADD"), attention deficit and hyperactivity disorder ("ADHD"), conduct disorder, sleep disorders, anger management, dementia, Alzheimer's disease, post traumatic stress disorder, or for mood enhancement or mood stabilization.

**Janssen's Marketing of Risperdal**

15. Federal and state laws allow physicians to prescribe FDA-approved drugs for conditions or diseases for which specific FDA approval has not been obtained when, through the exercise of independent professional judgment, the physician determines the drug in question is an appropriate treatment for an individual patient. This practice is referred to as prescribing for an "off-label" use.

16. However, under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., pharmaceutical manufacturers may not promote or market their products for any use not specifically approved by the FDA. This prohibited practice is known as "off-label marketing."

17. Janssen promoted Risperdal through the use of various marketing practices that were designed to result in the increase of off-label use of Risperdal. These practices included: setting sales goals and creating incentives that motivated sales representatives to promote Risperdal for unapproved uses; sponsoring and arranging speaker programs that promoted unapproved uses; conducting sham "consulting" programs in which physicians were paid to learn about Risperdal's unapproved uses; and rewarding physicians who prescribed and promoted Risperdal for unapproved uses with lucrative consulting agreements.

18. Despite having narrow FDA approval for Risperdal, Janssen promoted and marketed Risperdal off-label for the treatment of a variety of conditions and to a variety of patient populations for the treatment of conditions not included within the FDA-approved indications, including depression, anxiety, ADD, ADHD, conduct disorder, sleep disorders, anger management, dementia, Alzheimer's, and post traumatic stress disorder.

19. Through these marketing efforts, Janssen sought to enhance Risperdal's off-label market penetration across a wide range of diagnoses and patient populations, including child and geriatric patients who were unlikely to have indications for which the use of Risperdal had been approved by the FDA.

20. To expand Risperdal's use in the geriatric population, for example, Janssen created and deployed an "ElderCare" sales force in mid-1998, the purpose of which was to focus specifically on Risperdal's use to treat dementia in the elderly

21. While building its market for Risperdal, whether for on-label or off-label uses, Janssen also masked, withheld, or failed to disclose negative information contained in scientific studies concerning the safety and efficacy of Risperdal.

22. On November 10, 2003, for example, Janssen sent a form letter to thousands of health care providers to downplay any connection between the use of Risperdal and the development of diabetes. The letter stated, in part, "a body of evidence from published peer-reviewed epidemiology research suggests that RISPERDAL is not associated with a risk of increased diabetes when compared to untreated patients or patients treated with conventional antipsychotics. Evidence also suggests that RISPERDAL is associated with a lower risk of diabetes than some other studied atypical antipsychotics." The letter prompted the FDA on April 19, 2004 to issue a "Warning Letter" to Janssen, stating that the letter "misleadingly omits information about Risperdal, minimizes potentially fatal risks associated with the drug, and claims superior safety to other drugs in its class without adequate substantiation," in violation of the Federal Food, Drug, and Cosmetic Act.

## VIOLATIONS OF TEXAS DECEPTIVE TRADE PRACTICES-CONSUMER PROTECTION ACT

23. Defendants, as set forth above, in the course and conduct of trade and commerce, has directly and indirectly engaged in false, misleading, and deceptive acts and practices declared unlawful by §17.46 (a) and (b) of the Texas Deceptive Trade Practices-Consumer Protection Act, including but not limited to:

A. Causing confusion or misunderstanding as to the approval of the drug Risperdal, in violation of § 17.46(b)(2) of the DTPA;

B. Representing that Defendants' drug Risperdal has benefits which it does not have, in violation of § 17.46(b)(5) of the DTPA;

C. Representing that Defendants' drug Risperdal is of a particular standard, quality, or grade, if it is of another, in violation of § 17.46(b)(7) of the DTPA; and

D. Failing to disclose adequately the risks of Defendants' drug Risperdal, when such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed, in violation of § 17.46(b)(24) of the DTPA.

## INJURY TO CONSUMERS

24. By means of the foregoing unlawful acts and practices which were producing causes of injury to the persons affected, Defendants have acquired money or other property from identifiable persons to whom such money or property should be restored, or who in the alternative are entitled to an award of damages.

## CONTINUING VIOLATIONS

25. Defendants have violated and could continue to violate the laws as hereinabove alleged. Defendants, unless restrained by this Honorable Court, could continue violating the laws of the State of Texas. Defendants have violated and could continue to violate the Deceptive Trade Practices-Consumer Protection Act.

## PRAYER

26. WHEREFORE, PREMISES CONSIDERED, the STATE OF TEXAS prays that Defendants be cited according to law to appear and answer herein and that upon final hearing a PERMANENT INJUNCTION be issued restraining and enjoining Defendants and its agents, servants, employees, representatives, subsidiaries, divisions, successors, and assigns from making the representations, doing the acts, and engaging in the practices set out in the preceding paragraphs as well as from making the following representations and doing the following acts and engaging in the following practices in the pursuit and conduct of trade or commerce within the State of Texas as follows:

A. Causing confusion or misunderstanding as to the approval of the drug Risperdal;

B. Representing that Defendants' drug Risperdal has benefits which it does not have;

C. Representing that Defendants' drug Risperdal is of a particular standard, quality, or grade, if it is of another; and

D. Failing to disclose adequately the risks of Defendants' drug Risperdal, when such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed.

27. The STATE OF TEXAS further prays, that upon final hearing, this Court order Defendants to pay civil penalties of not more than $20,000.00 per violation, as provided in §17.47(c)(1) of the DTPA.

28. The STATE OF TEXAS further prays that the Office of the Attorney General be awarded their investigative costs, court costs, reasonable attorneys' fees, expenses, and witness fees pursuant to the laws of the State of Texas including the TEX. GOV'T CODE ANN. §402.006(c).

29. The STATE OF TEXAS further prays that upon final hearing that this Court grants all other relief to which the State may be justly entitled.

Respectfully submitted,

**Plaintiff State of Texas**

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